

## **BAYER MIGRAINE FORMULA- acetaminophen, aspirin and caffeine tablet**

**Bayer HealthCare LLC, Consumer Care**

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**Bayer Migraine Formula**

### ***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purposes</i></b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID*)	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

### **Use**

- treats migraine

### **Warnings**

#### **Reye's syndrome**

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

#### **Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

#### **Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

#### **Stomach bleeding warning**

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

- take more or for a longer time than directed

### **Caffeine warning**

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/ fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

### **Ask a doctor before use if**

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

### **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for:
  - anticoagulation (thinning of the blood)
  - diabetes
  - gout
  - arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur

- ringing in the ears or loss of hearing occurs

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

- **do not use more than directed**
- adults: take 2 caplets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

#### **Other information**

- store at 20° - 25° C (68° - 77° F)
- read all product information before using. Keep this box for important information.

#### **Inactive ingredients**

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, saccharin sodium, stearic acid, titanium dioxide

#### **Questions or comments?**

**1-800-331-4536** (Mon – Fri 9AM – 5PM EST) or [www.bayeraspirin.com](http://www.bayeraspirin.com)

Distributed by:

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Consumer Care

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#### **PRINCIPAL DISPLAY PANEL - 50 Caplet Bottle Carton**

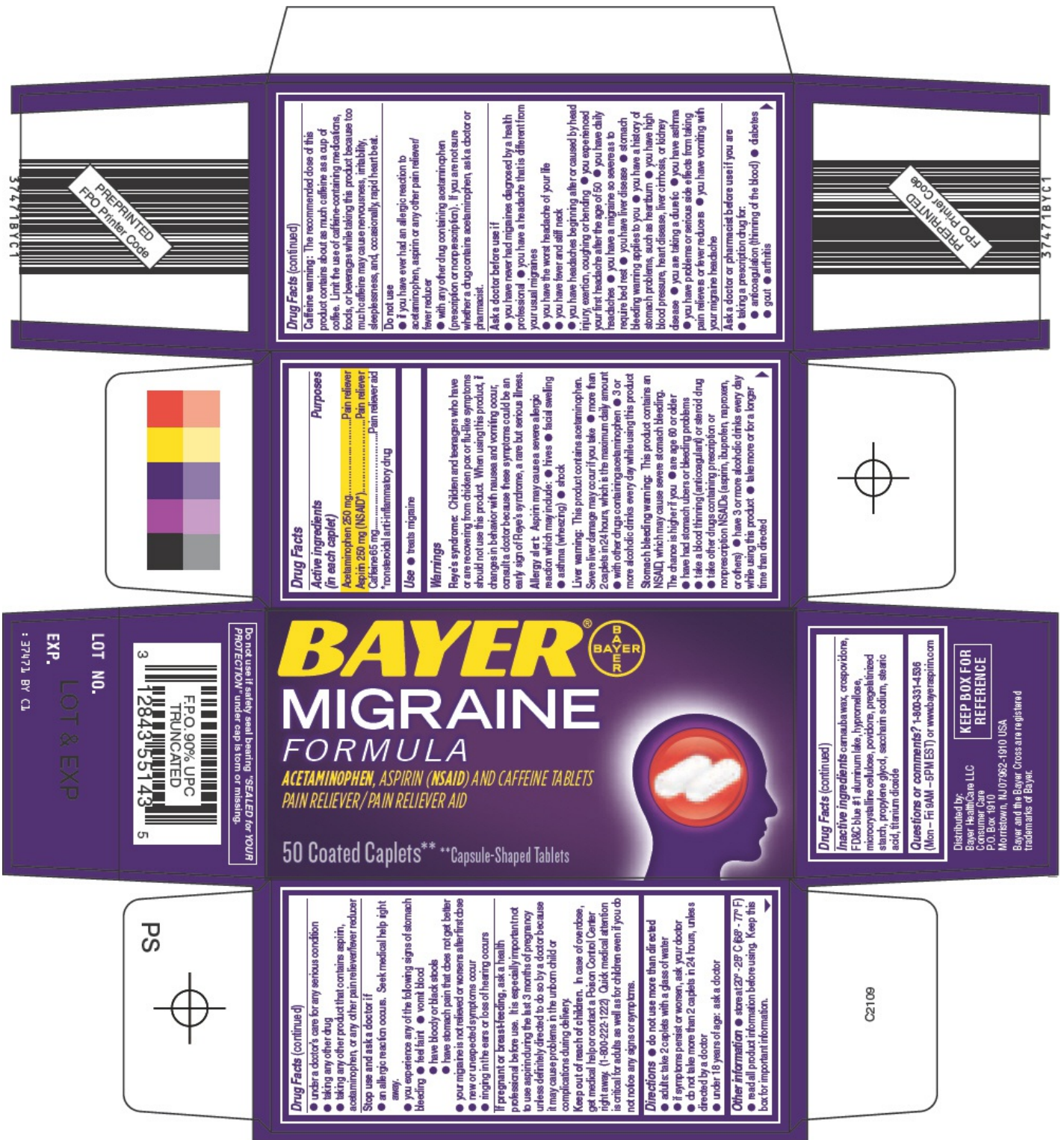
**BAYER®**

**MIGRAINE**

**FORMULA**

**ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE TABLETS**  
**PAIN RELIEVER/ PAIN RELIEVER AID**

**50 Coated Caplets\*\* \*\*Capsule-Shaped Tablets**



## BAYER MIGRAINE FORMULA

acetaminophen, aspirin, and caffeine tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-2030
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)			Acetaminophen	250 mg
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)			Aspirin	250 mg
Caffeine (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)			Caffeine	65 mg
Inactive Ingredients				
Ingredient Name			Strength	
FD&C blue NO. 1 (UNII: H3R47K3TBD)				
Carnauba wax (UNII: R12CBM0EIZ)				
Crospovidone (UNII: 68401960MK)				
Hypromelloses (UNII: 3NXW29V3WO)				
Cellulose, Microcrystalline (UNII: OP1R32D61U)				
povidones (UNII: FZ989GH94E)				
propylene glycol (UNII: 6DC9Q167V3)				
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)				
Stearic acid (UNII: 4ELV7Z65AP)				
titanium dioxide (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	BLUE	Score	no score	
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	L374	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2030-50	1 in 1 CARTON		
1		50 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA075794		06/26/2012	

**Labeler** - Bayer HealthCare LLC, Consumer Care (785159372)

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Bayer HealthCare LLC, Consumer Care